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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,540	03/01/2004	Hanson S. Gifford III	HRT-0256C2	2779

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EXAMINER

REIMERS, ANNETTE R

ART UNIT	PAPER NUMBER
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3733

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/790,540	GIFFORD ET AL.	
	Examiner	Art Unit	
	Annette R. Reimers	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 21-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 23, 2006 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 21-27, 34 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Richards (US Patent Number 4,887,601) , cited by examiner on 892, paper number 20060320.

Richards discloses various embodiments of a device for engaging tissue having a preexisting opening comprising an annular-shaped ring, e.g. 16A and 16B, having a

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width disposed about a longitudinal axis, and at least two staple members, e.g. 14, extending from and integrally formed with the ring, having a thickness extending from the ring each having a distal portion formed of an super elastic material, the distal portions having a first configuration, where the distal portions are separated by a first distance and wherein the distal portions are substantially parallel to the longitudinal axis, and a second configuration, where the distal portions are separated by a second distance, the second distance being less than the first distance, wherein the width of the annular-shaped ring is greater than the thickness of the staple members (see embodiments of figures 1 and 4-8, column 4, lines 21-38, 52-68, and column 5, lines 1-15). The first distance is greater than the diameter of the opening and the second distance is less than the diameter of the opening (see embodiments of figures 1 and 4-8, column 4, lines 21-38, 52-68, and column 5, lines 1-15). The distal portion of the staple members is substantially orthogonal to the longitudinal axis when the distal portions are in the second position and the distal portion has a sharpened point (see embodiments of figures 1 and 4-8, column 4, lines 21-38, 52-68, and column 5, lines 1-15). In addition, the distal portions are located radially inward relative to the annular ring when the distal portions are in the second configuration, and the distal portions of the staple members are not parallel with the longitudinal axis when the distal portions are in the second configuration (see embodiments of figures 1 and 4-8, column 4, lines 21-38, 52-68, and column 5, lines 1-15).

With regard to the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Richards,

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which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claims 21-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Tovey et al. (US Patent Number 5,478,354), cited by applicant on 1449, paper number 12212005.

Tovey et al. disclose various embodiments of a device for engaging tissue having a preexisting opening comprising an annular-shaped ring, e.g. 88 or 92, having a width disposed about a longitudinal axis, a tubular member, e.g. 99, a driver (see column 4, lines 39-40 and 55-56), wherein the drive and the are movable with respect to one another, and staple members, e.g. 84-86 or 94, extending from and integrally formed with the ring, having a thickness extending from the ring each having a distal portion formed of an super elastic and shape-memory material, the distal portions having a first configuration, where the distal portions are separated by a first distance and wherein the distal portions are substantially parallel to the longitudinal axis, and a second configuration, where the distal portions are separated by a second distance, the second distance being less than the first distance, wherein the width of the annular-shaped ring

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is greater than the thickness of the staple members (see embodiments of figures 8-11, column 4, lines 32-67, column 5, lines 47-59, and column 6, lines 20-37). The first distance is greater than the diameter of the opening and the second distance is less than the diameter of the opening (see embodiments of figures 8-11, column 4, lines 32-67, column 5, lines 47-59, and column 6, lines 20-37). The distal portion of the staple members is substantially orthogonal to the longitudinal axis when the distal portions are in the second position and the distal portion has a sharpened point (see embodiments of figures 8-11, column 4, lines 32-67, column 5, lines 47-59, and column 6, lines 20-37). In addition, the distal portions are located radially inward relative to the annular ring when the distal portions are in the second configuration, and the distal portions of the staple members are not parallel with the longitudinal axis when the distal portions are in the second configuration (see embodiments of figures 8-11, column 4, lines 32-67, column 5, lines 47-59, and column 6, lines 20-37).

With regard to the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Tovey et al., which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not

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differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Response to Arguments

Applicant's arguments with respect to claims 21-36 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette R. Reimers whose telephone number is (571) 272-7135. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER